

PATENT COOPERATION TREATY

PCT

10/562183

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference NEB-231-PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2004/017979	International filing date (<i>day/month/year</i>) 07 June 2004 (07.06.2004)	Priority date (<i>day/month/year</i>) 27 June 2003 (27.06.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant NEW ENGLAND BIOLABS, INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 03 January 2006 (03.01.2006)
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

TO: HARRIET M. STRIMPEL
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BEVERLY, MA 01915

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference

NEB-231-PCT

Date of mailing
(day/month/year)

28 FEB 2005

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/17979

International filing date (day/month/year)

07 June 2004 (07.06.2004)

Priority date (day/month/year)

27 June 2003 (27.06.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): G01N 33/53, 33/543 and US Cl.: 435/7.1, 7.92, 975; 436/518

Applicant

ZHANG, YINHUA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

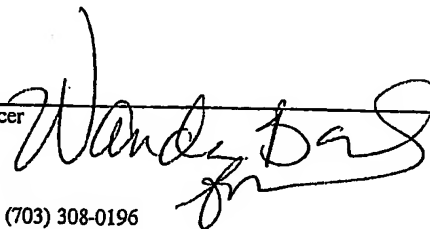
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Form PCT/ISA/237 (cover sheet) (January 2004)

Authorized officer

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/17979

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☐

in written format

☐

in computer readable form

c. time of filing/furnishing

☐

contained in international application as filed.

☐

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority for the purposes of search.

3. ☐

In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/17979

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>9-11, 13-15, 17, 19-22</u>	YES
	Claims <u>1-8, 12, 16, 18</u>	NO
Inventive step (IS)	Claims <u>9, 14, 15, 19-22</u>	YES
	Claims <u>1-8, 10-13, 16-18</u>	NO
Industrial applicability (IA)	Claims <u>1-22</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-8, 12, 16 and 18 lack novelty under PCT Article 33(2) as being anticipated by Tuse et al (WO 92/17786). Tuse et al disclose a method of detecting chitin. Tuse et al disclose reagents which bind specifically to chitin. Tuse et al disclose that the reagent can be immobilized to a solid support and used to capture chitin and subsequently detected by another specific reagent. (p. 10 and Figure 7). Tuse et al disclose packaging the components and reagents into a kit.

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Winters (US 5,004,699). Winters disclose monoclonal antibodies reactive with chitin used in an assay to detect chitin.

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Gray et al. (US 6,399,571). Gray et al disclose chitin binding reagents that are specific for chitin. Gray et al disclose that these reagents can be used in method for specifically identifying the presence of chitin in a sample (column 7).

Claim 10 lacks an inventive step under PCT Article 33(3) as being obvious over Gray et al in view of Harman et al (US 6,251,390).

Gray differs from the instant invention in failing to teach bleaching the sample.

Harmon et al teaches bleaching of a sample to purify the chitin.

It would have been obvious to one of ordinary skill in the art to bleach the sample of Gray et al because Harmon et al teaches that bleaching of the sample provides for purification of the sample.

Claim 11 lacks an inventive step under PCT Article 33(3) as being obvious over Gray et al in view of Comb et al (US 5,834,247).

Gray et al. differ from the instant invention in failing to teach the CBD is obtained from chitinase A1 from *Bacillus circulans*. Comb et al teaches obtaining a CBD from *Bacillus circulans* WL12 Chitinase A1 (col. 73).

It would have been obvious to one of ordinary skill in the art to obtain the CBD binding domain as taught by Comb et al for the method of Gray et al because Gray et al teaches obtaining the CBD from organisms and one of ordinary skill in the art would have a reasonable expectation of success using a CBD as taught by Comb et al in the method of Gray et al.

Claim 13 lacks an inventive step under PCT Article 33(3) as being obvious over Tuse et al.

It is very well known in the art to use instruction for performing assays and thus it would have been obvious to one of ordinary skill in the art to include instruction in a kit for performing an assay.

Claim 17 lacks an inventive step under PCT Article 33(3) as being obvious over Tuse et al and Gary et al as applied in the preceding paragraphs and further in view of Comb et al.

See above for teachings of Tuse et al., Gray et al and Comb et al.

Claims 9, 14, 15 and 19-22 meet the criteria set out in PCT Article 33(2)-(3), because the prior art of record does not teach or fairly suggest the CBD has a carbohydrate-binding module corresponding to CBM12 or the carrier protein is maltose-binding protein.

Claims 1-22 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.